IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VERAX BIOMEDICAL INC.,	)	
	)	
Plaintiff	)	
	)	
-VS-	)	CA No. 23-10335-PBS
	)	Pages 1 - 67
AMERICAN NATIONAL RED CROSS,	)	
	)	
Defendant	)	

MOTION HEARING BY VIDEO

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way
Boston, Massachusetts 02210
September 28, 2023, 9:34 a.m.

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OFFICIAL COURT REPORTER
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A P P E A R A N C E S:

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P R O C E E D I N G S

THE CLERK: Good morning.

THE COURT: Good morning.

THE CLERK: So I have everybody on on both sides, and I'll call the case.

THE COURT: Thank you.

THE CLERK: You're welcome. The Court calls Civil Action 23-10335, Verax Biomedical Inc. v. American National Red Cross. Could counsel please identify themselves.

MR. ABELES: Scott Abeles from Carlton Fields for Verax, and joining me today, also from Carlton Fields, is Ben Stoll.

MS. GIORDANO: Good morning, your Honor. Jennifer Giordano from Latham & Watkins on behalf of the defendant, American National Red Cross.

MR. ADAMSON: Good morning, your Honor. Joseph Adamson from the U.S. Department of Justice representing the United States of America.

THE COURT: Thank you. Do we have everyone? All right, so we have two hours for this, and I was trying to think of how we can divide this up in a practical way. Was the United States planning on arguing?

MR. ADAMSON: If your Honor allows, we would like to speak. We prepared for that ten minutes, but hopefully it will require less time than that.

THE COURT: It strikes me that the arguments fall into three buckets. Maybe there are more. I mean, the first would be, is the American Red Cross a person? And we could spend -- each side could maybe have ten minutes apiece? Does that make sense? Then the U.S. can either watch, enjoy, or leave. That's fine. Then there's the big buckets of the antitrust allegations, and then there are the state tort claims.

So have you figured out -- I think it makes sense to go through those three buckets rather than have each person 09:37 argue nonstop, but I don't know if you've proposed another agenda.

MR. ABELES: That approach, dealing with personhood first and then the antitrust claims and then the state law claims, sounds like a good approach to us, your Honor.

MS. GIORDANO: Yes, your Honor, that sounds like a good approach to the American Red Cross as well, your Honor. I confess, I feel that I might need a little bit more than ten minutes to present the argument but not a whole lot more, if that would be okay, on personhood.

09:37 THE COURT: Well, how long do you think you'd need?

MS. GIORDANO: Fifteen minutes?

THE COURT: Done. Easy win. The other issue is much harder. So let me just warn you that that essentially means -- so basically it's in the vicinity of forty-five minutes for the personhood issue, and then, if I do that, it strikes me that

antitrust may be the hardest in some ways, or at least the most diffuse; and it just may be you'll have to, if we don't finish, end up on your papers in the state tort claims.

So let's just try for it. I mean, I don't know that you can do justice to the antitrust issues in less than fifteen minutes apiece. My guess is much longer, right?

MS. GIORDANO: I think that we can deal with the antitrust issues in the remaining time that we have, and American Red Cross would be comfortable resting on our papers on the state law claims if we run out of time, your Honor.

09:38

MR. ABELES: We would as well, your Honor.

THE COURT: Okay. And let me just say, I actually don't think the State Court claims are so easy, some of them. If I really feel the need for a further argument, if I plow my way through these, I may just ask for just a second argument, so maybe I'll see you and you'll have travel expenses, okay? All right.

All right, so why don't we start on -- I suppose what we can do -- it's a motion to dismiss, so technically we should start with the American Red Cross. And I'll be mean and cut you off in fifteen minutes because otherwise we'll never get through all this. Okay?

09:39

MS. GIORDANO: Fair enough, your Honor. Thank you so much.

THE COURT: So it's now -- I have roughly 9:40, okay?

MS. GIORDANO: Your Honor, we have a few slides. I know you have a copy of them in front of you. Would it be okay if I presented them on the screen now?

THE COURT: Of course.

MS. GIORDANO: Thank you. I'm going to be starting on Slide 4 for your reference for your hard copy. Can you see the slides okay?

THE COURT: Yes.

MS. GIORDANO: Okay, thank you. So good morning, your
09:40 Honor. As I said, I'm Jennifer Giordano, and I represent the Red Cross in this matter, and this personhood argument that we're starting with today is the question of which entities fall within the definition of the statutory term "person" under the Sherman Act? Because Congress has determined that only persons can be sued under that Act. And the courts have been called upon to interpret the definition of the term "person" a number of times over the years, and with respect to the issue in this case, all the courts who have considered the question over the last forty years have concluded that the United States
09:40 government and its federal instrumentalities are not persons within the meaning of the Sherman Act.

I put a sampling of those cases on Slide 4. These are not all of them, but I just wanted to highlight -- these are all cited in our brief -- that the term "instrumentality, "government instrumentality, instrumentality of the United

States," it's basically a term of art in this body of law.

And I would note that the Department of Justice itself has said that in fact federal instrumentalities are not persons under the Sherman Act. This is really an uncontroversial proposition.

The two most famous cases that get discussed the most, of course, start with *Sea-Land*, which was the DC Circuit's decision from 1981. That was a decision written by then Judge Ginsberg when she was sitting on the DC Circuit, and the 09:41 DC Circuit concluded that Congress did not place the United States or its instrumentalities under the governance of the Sherman Act.

Move forward to 2004 when the Supreme Court took up this question in the *U.S. Postal Service v. Flamingo* case. At that point in time, Justice Ginsberg was now a sitting member of the Supreme Court, and I'm sure she was delighted to hear that her entire set of colleagues unanimously agreed with her that she had gotten it right in *Sea-Land* and that *Sea-Land* had set forth the correct approach to this "person" question, 09:42 holding that the Sherman Act definition of "person" does not include the United States or federal entities, and that meant that the Postal Service was not a person that could be sued under the Sherman Act.

This body of law I just described to you about federal instrumentalities, that the principle, the legal principle that

federal instrumentalities are not subject to the Sherman Act is a settled issue, but there is sometimes debate about which entities constitute federal instrumentalities when Congress has not formally designated them as such. And in fact that was really the thrust of the central debate in the *Flamingo* case. The Department of Justice said over and over again that federal instrumentalities are not persons because it was trying to convince the Supreme Court to treat the Postal Service as a functional equivalent of a federal instrumentality, even though 09:43 Congress had not formally designated it as such. Congress had designated the Postal Service as an independent establishment of the Executive Branch.

But this instrumentality doctrine is so well-ingrained in the courts that, as I showed you on Slide 4 at the very bottom, the Third Circuit itself characterizes the *Flamingo* case as holding that the Postal Service is a federal instrumentality for antitrust purposes.

Fortunately here, we don't have to engage in the debate about what the Red Cross is and whether it should be 09:43 treated as a federal instrumentality because Congress has formally designated it as such.

So Verax says that the Court should not let the Red Cross escape the antitrust laws just because it does good deeds. There are a lot of good-deed-doing companies that are subject to the antitrust laws, and that is certainly true, but

the Red Cross is fundamentally different than those organizations in a couple of important respects. The first is that it exists and it is organized pursuant to a statutory charter blessed by Congress right in the United States Code. It's Title 36 of the Code, Section 300101.

And importantly for this case, in 2007 Congress, passed by both the House and the Senate, amended the Red Cross's statutory charter to confirm that it is in fact a federally chartered instrumentality of the United States; and

09:44 in that Act amending the charter, which is known as the 2007 Governance Act, Congress said not once but twice, "Let us be clear that we want the Red Cross to have the rights and obligations consistent with federal instrumentality status." So under the body of law I just described to you, that means the Red Cross is not a person.

Now, the reason that Congress has designated the Red Cross as a federally chartered instrumentality of the United States is because Congress has given the Red Cross incredibly important obligations for this country. We cited these in our

09:45 brief, so I won't go over them. You are all probably familiar with the fact that the Red Cross does a lot of humanitarian work, disaster relief work, but I, for one, was not aware that those obligations actually emanate from a statute that Congress has imposed on the Red Cross to do these things.

I want to pause for a moment on the two middle bullets

on Slide 8 because these are things that Congress obligates the Red Cross to do that may not be as familiar to some of us. The first is that Congress has given the Red Cross incredibly important obligations with respect to our U.S. military, both our active-duty members, the veterans, and our wounded soldiers.

Congress has also designated the Red Cross to fulfill the United States's treaty obligations under things like the Geneva Convention. In fact, Congress views the Red Cross's treaty obligations as so important that it has actually created an entire subsection of the U.S. Code just for the Red Cross that is defined as "Treaty Obligation Organization." It is a party of one; it's just the Red Cross.

09:46

I want to pause just briefly on this treaty issue for a moment because I know it has come up, both by the Department of Justice and by Verax, as somehow the Red Sox's treaty obligations are a reason it is not part of the government. I think it was DOJ who even went so far as to say that those treaties legally require the Red Cross to be structurally

09:46

separate from the United States government, and I confess I have no idea where they're getting that from. That's just not true. The treaties do not require the Red Cross to be structurally separate from the United States government, and in fact, it's actually getting things backwards. The whole reason that Congress gave the Red Cross its first statutory charter in

1900 -- that's the first one -- was because Congress was designating the Red Cross as the United States's representative under the Geneva Convention, and Congress said that's so important, that work is so important for this country that it demands that we bring the Red Cross into the government, create it as a federal entity, and that we bring it under federal government supervision.

The Red Cross, of course, as you know from our papers, existed prior to 1900. Clara Barton famously founded it in 09:47 1881. It was an entity, and Congress said "That thing, that form that Clara Barton found isn't good enough for our purposes. We need to re-charter it --" that's the word it used -- "recreate it as a federal entity," and that's how this whole thing started.

So I think these facts show us that under a straightforth interpretation of the Supreme Court's decision in *Flamingo,* the Red Cross is simply not a person.

THE COURT: So was the Post Office a corporation?

MS. GIORDANO: The Post Office was not a corporation. 09:48 It was an independent establishment of the Executive Branch.

THE COURT: So were any of these federal instrumentalities not subject to the various laws, are any of them actual corporations?

MS. GIORDANO: Yes, an important one actually, your Honor, and I will flip to that slide, if I can, if I remember

what page number it was. I think it's 14. The Federal Reserve Banks, those are designated statutorily as federal corporations and only federal corporations. They are not statutorily designated as federal instrumentalities. Yet the Sixth Circuit held that the Federal Reserve Banks are not persons under the Sherman Act, and I believe that is a holding that the Department of Justice agrees with. At least that's what their papers said.

And another example is the Ninth Circuit case in *Sakamoto*, which I'll go back to Slide 4 so you can see the cite. That is a case where the -- I believe it was the Guam Airport Authority, that was the instrumentality at issue there, statutorily that was designated as a corporation, not as a federal instrumentality, but it was still held not to be a person. The same is true, of course, with the *IT & E Overseas* case, the District of DC case in 1990.

09:49

09:49

THE COURT: Thank you.

MS. GIORDANO: Okay, I wanted to make clear another point about *Flamingo* that I wanted to clear up here, which is, I think it's apparent from a reading of *Flamingo*, but there are a lot of cases that Verax and DOJ cited about sovereign immunity. Those cases are not relevant here. There's no dispute that Congress has waived the Red Cross's sovereign immunity. We don't dispute it. We agree that that has happened. I can assure you, I'd be arguing something very

different if it had not, but we go to the second step. What *Flamingo* says is, just because Congress has waived a federal entity's sovereign immunity does not mean that entity is a person under the Sherman Act. The question we ask is, is that entity a part of the government for Sherman Act purposes, or is it a wholly private entity that exists outside of the government? That's our task. And to answer that question, the Supreme Court tells us we look to the statute because this is fundamentally a question of statutory interpretation. We're trying to discern, what did Congress intend the Red Cross to be for purposes of the Sherman Act?

09:50

Now, there's sort of a simple analytical framework *Flamingo* lays out. You look at the organizing statute for the entity. Here, that's Title 36 for the Red Cross. You look at the statutory designation that Congress gave to the entity, here federal instrumentality of the United States. And, three, once you've determined that that statutory designation is as a federal entity, that sort of ends the question for Sherman Act purposes unless Congress has given you an express statement that this particular federal entity is subject to the Sherman Act. In other words, Congress has to say, "Despite being a federal entity, we want the Red Cross to be subject to the Sherman Act," and it has not done that here.

09:51

Now, *Flamingo* did go on to talk about some features of the Postal Service statute that showed basically that in fact

the Postal Service was a public organization, that Congress had given it national responsibilities and had given it different obligations/rights than private entities; and I don't think you need to do that here because I think that the statutory designation from Congress puts the Red Cross comfortably in the body of law that says it's not a person. But even if you wanted to go looking in the Red Cross statute for whether Congress has given it, quote, "nationwide public responsibilities" and "different goal obligations and powers from private corporations," you would see that Congress has given plenty of those things to the Red Cross. I won't go over all of them in the interest of time. They're in our brief. But as you can see, this is a very dense slide because there's lots of things in the statute that show that Congress made the Red Cross a public organization, not a private one.

09:52

THE COURT: Who pays for the Red Cross other than people who contribute privately through philanthropy?

MS. GIORDANO: So the Red Cross receives primarily money from donations and also from cost-recovery charges that it receives back when it provides products and sells products to people. It's a nonprofit organization, but there are some products -- for example, in its blood products business -- that it receives cost-recovery charges so it can recover the costs of manufacturing those products.

09:52

THE COURT: Taxpayer dollars don't pay for it?

MS. GIORDANO: Not ordinarily. Sometimes there are appropriations from Congress to the Red Cross. From time to time, they do give money to the Red Cross for certain projects. But Congress actually relies on the Red Cross to do all these critically important national responsibilities for this country at really no expense to the federal government, right? So if we think about the types of entities that Congress would want to make sure were not subject to the Sherman Act, were not subject to treble damages, an entity like the Red Cross that it
09:53 is relying on, that currently it doesn't have to find funding for, is relying on to do all these public responsibilities but currently doesn't have to have funding for, imagine a scenario where the Red Cross were subject to treble damages, and then suddenly it didn't have enough money to do all those obligations that Congress needs it to do, Congress is going to have to find the money to do these things. These are critically important things for this country, and if the Red Cross doesn't do them, Congress is going to have to pay for them. So you could easily see why Congress would not want the Red Cross to be subject to
09:54 the Sherman Act.

THE COURT: All right, so you've pretty much run out of time, but I have one question for you: If I resolve this in your favor, I'm assuming the rest of the antitrust cases go away but the state cases don't. State common law cases would have to be separately resolved, right?

MS. GIORDANO: That is -- well, I think the 93A claim, to the extent it was based on the federal Sherman Act theory, that would fall; but if the 93A claim is based on the state claims, you are correct, that is true. An actual quirk of this whole process is that Congress thinks the Red Cross is such a federal entity that it has created original federal jurisdiction in Federal Court for all claims against the Red Cross. Normally I would be arguing to you, when the federal claims go away, you should not exercise jurisdiction over the state law 09:55 claims, but the reality is, this is such a federal entity that Congress has said, everything it does is so federal that all claims against it are heard in Federal Court, not State Court; and actually that was a ruling of the Supreme Court in 1992.

THE COURT: So if I thought that the Red Cross was doing something, say, unconscionable, or I forget the other state tort claims, those all have to be separately resolved regardless of whether it's a federal instrumentality or not?

MS. GIORDANO: The State Court claims, yes, would have to be resolved regardless of whether it's a federal entity, 09:55 that is true.

THE COURT: All right, you're out of time, so thank you very much.

MS. GIORDANO: Okay, thank you. I will stop sharing.

THE COURT: Thank you. Verax? Yes, there we go.

MR. ABELES: Okay, and since we're starting in the

middle, I'm starting on Slide 13, your Honor.

Good morning. So ARC is in fact a person under the Sherman Act. The Sherman Act imposes liability on every person who violates it. Persons include corporations. ARC is a tax-exempt corporation. It has a billion-dollar private blood-related business. I'm going to address the argument that the United States's instrumentalities are automatically considered the United States under the Sherman Act, and, in the course of doing that, talk about a lack of control the nation
09:56 exercises over ARC, the lack of evidence that Congress under the Sherman Act or the Red Cross Act intended to make ARC a nonperson, and remind you that, you know, while in the Sherman Act it's not been tested, this principle has been tested in other areas of the law in which the holdings have been that the Red Cross is a corporate person separate from the United States.

So ARC plays down its corporate status, but in *Flamingo* it was an important consideration. "The Postal Service is part of the government," the Court said, "but if
09:57 Congress chose to create it as a federal corporation, then you would have to do further analysis." It's correct, like the example of the Federal Reserve Banks, corporate status does not automatically make you a person but points in that direction; and we pointed out in the *Tennessee Valley* case that the Sixth Circuit picked up on this and said -- and this is a key

distinction between us and *Flamingo*, between the Tennessee Valley Authority and the Postal Service, is that the Tennessee Valley Authority is a federal corporation, unlike the Postal Service. It's true that the court then ruled against the defendant on other grounds, but the point is, it is --

THE COURT: Well, did it hold it was subject to antitrust? It did.

MR. ABELES: Yes, it did, but, yes, for a different reason, not because it was a corporation, but there was an

09:58 alternative reason.

THE COURT: So what did the --

MR. ABELES: I'm sorry?

THE COURT: -- the circuit hold, that TVA was subject to antitrust or was not?

MR. ABELES: That it was, that it was.

THE COURT: Yes.

MR. ABELES: Yes. And so, your Honor, there's this argument that was just presented that instrumentalities are automatically nonpersons under the Sherman Act unless there's

09:58 this separate Congressional statement, but there are numerous cases that say that the U.S. -- their immunity from law does not automatically extend to instrumentalities, and if it did, *Flamingo* would be a lot shorter, okay? It wouldn't have a two-part test; it would have a one-part test: Are you an instrumentality? Yes. You're not a person. That is not the

holding of *Flamingo*.

And *Sea-Land* does not hold otherwise. That was discussed as well. This is the then Judge Ginsberg case. That's a case that's very distinguishable from this one. It's a railroad owned and operated by the government in which the holding -- the slide presented by the defendant talked about as a matter of law. This is the holding right here: "We hold that the United States, its agencies and officials," meaning outside of the Sherman Act, and that holding is confirmed by Flamingo. "The DC Circuit recognized the two distinct inquiries required when the question is whether the government, or an entity it owns, is named as a defendant in a suit under the antitrust laws." That's where *Sea-Land* has persuasive value, not here.

09:59

So the real test under *Flamingo* is, you first evaluate whether there's a waiver of sovereign immunity, and there is here, so we move on to the second part, which examines whether the substantive prohibitions of the Sherman Act apply to the entity in question.

10:00

ARC has a different test. We just talked about it, but their test is the quote from their brief: "Congress' statutory designation of a federal instrumentality renders that entity not a person under the Sherman Act unless there's an express statement from Congress." But when you look at *Flamingo*, that is not what *Flamingo* says. That is a mis-

reading of *Flamingo*.

And I'm going to show you the next slide, and there's other considerations that are mentioned in the bullet, but what *Flamingo* says -- this is what they're quoting from -- "The silence in the Postal Act leads to no helpful inference one way or the other, but the other considerations --" we'll talk about them in a second -- "the other considerations we have discussed lead us to say that absent an express statement from Congress, the PRA does not subject the Postal Service to antitrust liability."

10:01

According to the Red Cross, the only consideration -- see right above -- is the statutory designation, but that is not what *Flamingo* -- we know that's important, but there's a lot of other important things. This does not come after that discussion, your Honor. This comes before. This is on Page 741 in *Flamingo*. The relevant quote here is on 746.

So under the PRA, So what are the other considerations? The Postal Service retains its monopoly. Another consideration, it has the right to search and seize.

10:02

Another consideration, it's got to provide universal service. Power of eminent domain, regulatory powers, international obligations, all that shows is, as this brief summary indicates, the Postal Service has significant government powers consistent with the status as an independent establishment --

THE COURT: The Red Cross has some of those obligations,

right?

MR. ABELES: It has a few. It has some obligations.

THE COURT: I mean, this is a case of first impression; am I right? No court in the country has ruled on it?

MR. ABELES: Well, it's not ruled on whether the Red Cross is subject to the antitrust laws, but I agree with you, your Honor; I have not dealt with issues that are completely on par with the ones that you are presented with. But the concepts, the concepts have been discussed at length, as in *Flamingo* and some of these other cases.

And so if I may, your Honor, this last sentence is important. It says, "With respect to antitrust liability, the PRA neither exempts the Postal Service nor subjects it to liability." It is silent on the point. And where did we just see that silent point? Right here, right here in this area of the case that the ARC focuses on. The silence in the PRA leads to no helpful inference, but there are other considerations. They are clearly talking about the same thing. What are those other considerations? Well, we have the silence, but we have all of these considerations. So this test that the Red Cross posits is just not the test. It's not a proper reading of *Flamingo*.

And, look, when it comes down to it, none of those considerations are here, your Honor, save for the one that you

just mentioned about some international obligations, but it's not an independent establishment of the Executive Branch. And let me just make the point. When we talk about an independent establishment --

THE COURT: So let's say you win your points and you get treble damages, does that essentially mean the Red Cross can't serve the military?

MR. ABELES: No, your Honor. I mean, this is a billion-dollar business that they run. They make an awful lot 10:04 of money, and I doubt that Congress will allow our military to suffer because of this case, but -- so, no, I don't believe so.

THE COURT: This is a very close call here, isn't it? I mean, it's hard.

MR. ABELES: I appreciate the position you're in, your Honor, but I don't believe that it's a difficult call because the real test looks for what form the defendant takes, is it a corporation? And not dispositive but directionally important. And would Congress have intended the Sherman Act to cover this entity? And you can see, I mean, they give the Postal Service 10:05 a monopoly. How do you enforce the antitrust laws against an entity that you grant a monopoly that doesn't set its own prices and so forth? And what the Red Cross says is, the price-setting, that doesn't matter. That's exactly what they're saying. It also does not matter, as Verax claims -- as Verax claims -- that the Red Cross sets prices for blood

products. Now, we did claim that, but we were quoting *Flamingo*. It's *Flamingo* that claims that this is important: "The Postal Service lacks the prototypical means of engaging in anticompetitive behavior: the power to set prices." I think in an antitrust case, the prototypical means of engaging in anticompetitive behavior matters.

And, look, you know, we mentioned this before, your Honor, and the DOJ did as well, that the Red Cross is not in the Sherman Act, fair enough, your Honor; but in other areas of law, when the issue has been presented, the courts have generally concluded that ARC and the United States are separate. And that's my argument on this issue, your Honor.

THE COURT: Thank you. So the government, DOJ.

MR. ADAMSON: Yes, good morning, your Honor. My name is Joseph Adamson again.

THE COURT: Why don't we take down your slide from Verax.

MR. ABELES: Oh, sure.

THE COURT: Perfect, because I could barely see you. You were disappearing off my screen.

MR. ADAMSON: Thank you, your Honor. Again, my name is Joseph Adamson representing the United States, and I want to thank you for the opportunity for the United States to file a statement of interest in this matter and to speak today. The United States filed a statement of interest because it has an

interest in insuring the correct application of the antitrust laws. I want to reiterate --

THE COURT: Excuse me. Are you from the Antitrust Division?

MR. ADAMSON: Yes, I am, and I want to reiterate what we stated in our brief, that we take no position on the merits of the complaint or the other arguments raised in the motion to dismiss briefing, other than the Red Cross's argument that it is a part of the United States and is not subject to the Sherman Act.

Our position, the position of the United States, is that the American National Red Cross is no part of the United States but is a person subject to the Sherman Act. And hopefully I won't rehash too much of what you've already heard, but under the controlling case, *Flamingo*, the Red Cross is not part of the United States because the United States lacks control, ownership, and oversight of the Red Cross. The President does not appoint any of the Red Cross's governors, and the Red Cross also lacks the governmental characteristics, such as powers of eminent domain or the power to issue regulations, the courts have found relevant to analyzing whether an entity is a part of the United States for the purposes of the Sherman Act.

The relevant law starts with the Sherman Act. The Sherman Act includes, among its definition of persons who are

subject to the Act, corporations like the Red Cross. The Red Cross contends that because Congress --

THE COURT: Well, the Red Cross is a hybrid, right? That's what makes it so hard. I mean, it does have certain governmental functions, but it also acts like a private actor in setting prices. It's a very difficult issue.

MR. ADAMSON: Well, I understand your question, your Honor. We think under the proper analysis under *Flamingo* --

THE COURT: What do they call those men in mythology, half men, half horses? I mean, it's sort of -- I don't know, it just strikes me as if it's a very -- no one has really ruled on it, and they do have some aspects of being a governmental entity. They're called a federal instrumentality. On the other hand, a lot of the powers you usually think of they don't have.

What is DOJ relying on? In the Antitrust Division, would it feel empowered to prosecute or sue the American Red Cross? Has it ever thought about that?

MR. ADAMSON: I don't know if it has ever happened in prior Antitrust Division, but under the reading in *Flamingo* and under the text of the Sherman Act, the United States believes that it's clear that the Red Cross is not a part of the government due to the lack of government oversight and control.

And, again, because the Red Cross is acting here in this matter -- its blood product business engages in hundreds

of millions or billions of dollars of commerce annually -- that is a significant area of commerce that they're looking to remove from oversight of the competition laws, the antitrust laws in this country. So --

THE COURT: Well, can I ask, if I took them out of antitrust liability, are they subject to control at all by the Federal Trade Commission or by any other entity, or are they basically free to do what they want?

MR. ADAMSON: They're not subject to control by the government outside of, in the context of competition, outside of the application of the Sherman Act for them.

THE COURT: So the FTC wouldn't have jurisdiction either?

MR. ADAMSON: If they're not subject to the Sherman Act as part of the United States, then I, uhm --

THE COURT: Anyway, maybe I caught you unawares, because it is troubling that on the one hand, if you found the antitrust liability, you could put them out of business for purposes of their international and military obligations. On the other hand, if you don't find it, they can do whatever they want anticompetitively, and the government has no control over it. It's sort of a difficult position, right?

MR. ADAMSON: Well, your Honor, I guess in the context of that question, there are dozens, hundreds, probably thousands of private corporations that do significant business

and provide services to the U.S. military who are all subject to the Sherman Act and subject to the antitrust laws.

THE COURT: Okay. So it's the position of the Department of Justice that it's subject to Sherman?

MR. ADAMSON: Yes, it is, your Honor.

THE COURT: And other than *Flamingo*, is there any key case that you would bring my attention to, and *Sea-Land*?

MR. ADAMSON: Yes, your Honor. So *Flamingo* controls here, and under *Flamingo,* the Red Cross's reading is a misreading. *Flamingo* did not rest at Congress' designation of the Postal Service as an independent establishment of the Executive Branch of the United States. The court considered that as one factor, but the whole analysis of the Postal Service's connections to the government in terms of oversight and control, the powers of Presidential appointment over the Board of Governors, as well as powers that Congress had granted to the Postal Service, such as the powers of eminent domain or the power to issue appropriate regulations, as well as limitations that Congress had imposed on the Postal Service such as on the power to set prices, and here none of those factors apply to the Red Cross.

And going back to *Flamingo*, after analyzing all of those factors and not just Congress' designation of the Postal Service, the Supreme Court concluded in *Flamingo* that in form and function, the Postal Service was a part of the United

States.

And it's also important to note, as counsel for Verax noted, that when the Supreme Court considered Congress' designation of the Postal Service, it did note that its analysis would be different if Congress had designated the Postal Service -- had created the Postal Service as a corporation, and that is because corporations are explicitly included among persons who are subject to the Sherman Act. The Sherman Act does not mention instrumentalities anywhere in its text. *Flamingo* does not mention instrumentalities anywhere in its text.

And the Supreme Court's endorsement of *Sea-Land* as, again, counsel for Verax pointed out and put up on their slides, the endorsement of *Sea-Land* and *Flamingo* was limited to its proper application of the two-step analysis to determine whether an entity could be sued and then whether it was subject to the acceptance of law in question.

THE COURT: All right, thank you.

MS. GIORDANO: Your Honor, may I just have ninety seconds to respond? I promise I can do it in ninety seconds.

THE COURT: Ninety seconds you have. But don't forget, every second -- you know, there's very complicated antitrust case issues as well.

MS. GIORDANO: Yes, I will happily take ninety seconds from my antitrust argument. One point one, in the *Flamingo*

case at Page 747 to 748, the Supreme Court recognized the Postal Service has lines of business for which it sets prices independently and for which it operates for profit. That did not trouble the Supreme Court because it found overall the Postal Service was part of the government and not a person.

Number two, you asked, well, what would happen here if you did not subject the Red Cross to the Sherman Act, there would be no control? Congress has control here, your Honor. It simply has to say -- if it wants the Red Cross to be subject to the Sherman Act, it simply has to say so, so they control the outcome.

THE COURT: Congress, I mean, they don't do oversight hearings. So you mean you're going to try and get a majority of each house? That's your control? I mean, it's not like there are oversight hearings or anything like that.

MS. GIORDANO: They have a lot of oversight and a regular supervision of the Red Cross.

THE COURT: Do they? Do they have hearings, oversight hearings?

MS. GIORDANO: Not hearings, but there are reports to ten separate members of Congress every year about everything the Red Cross is doing, every dollar it's spending and every dollar it's taking in.

THE COURT: By request or by --

MS. GIORDANO: By statute. I go back to my slide.

They have ordered the Red Cross to file every year. The Secretary of the Department of Defense audits our financials, and those are reported to Congress. There is an annual report on everything we do, including all of our blood business, to ten separate committees in Congress, five in the House, five in the Senate every year. They know everything that we're doing every year. There's a lot of --

THE COURT: That's helpful. Okay, end because we have so much to do.

10:16 MS. GIORDANO: Thank you, thank you, thank you.

THE COURT: So it's now 10:15. I have another hearing at 11:30, which is why that becomes a hard stop. So if the government -- thank you very much -- I'm going to ask you to turn off your camera. All right, thank you very much for participating.

So I think at this point, half an hour, half an hour, does that make sense on the antitrust? And maybe a blurb afterwards on the state law claims. And I also have to give my court reporter a break between the two hearings. So, all

10:17 right, let's go.

MS. GIORDANO: Okay, thank you, your Honor. So putting aside the question of whether the Red Cross is subject to the Sherman Act, even if it is, we believe there's independent reasons why the Red Cross is -- these antitrust claims still fail on their merits, and I'm going to touch on those specific

reasons in a moment. But there's a core nucleus of undisputed facts here that I want to talk about first because it's this core nucleus of facts that are not in dispute and are, frankly, indisputable that is the reason Verax's antitrust claims fail for multiple different reasons, so if you can just bear with me for a moment because I think it's important to understand these facts. And, honestly, I'll be candid: This is a hard subject area to understand, at least it was for me in the first instance.

This is a case about platelets, which is a blood product. It is the cell fragments in blood that cause clotting, okay, so this is a really important medical product. It saves lives on a daily, if not minute basis every day. The unique thing about platelets is that they have to be stored at room temperature. They can't be frozen or refrigerated, and that means they have a very short shelf life. So from the time you take the platelets out of the donor's arm to the time that they have to get into a patient is, for Red Cross platelets, five days or less. Sometimes it can be seven days. It's never more than seven days. So you have one week or less to get these things into patients, so that's a pretty big deal.

They are also, because it has to be stored at room temperature, susceptible to bacterial contamination; and if you transfuse platelets that have bacteria in them into a patient, that can cause many bad things to happen, including such disastrous outcomes like sepsis and death.

So it's no surprise that platelets, like most blood products, are heavily regulated by the FDA. I'm just going to put my slides up here again for your benefit. Can you see them?

Okay, there are many rules and regulations that apply to all blood products and that apply to platelets. This case happens to only involve just one. It's 21 CFR, Section 606.145, and this is a regulation that applies to all blood collection establishments, which includes the Red Cross. And it says that --

10:19

THE COURT: So you're not -- I did have that question -- you're not considered a transfusion service?

MS. GIORDANO: We are a blood collection establishment. we don't transfuse.

THE COURT: Okay, you never transfuse. Okay.

MS. GIORDANO: No. But, of course, the regulation says this is an obligation: We must assure that the risk of bacterial contamination is adequately controlled -- it's not optional -- and we have to do so using FDA-approved techniques.

10:20

This is not in dispute here at all, your Honor. And in fact there's no dispute here that to date, the FDA has only approved three methods for the Red Cross to satisfy its obligations under Section 606.145. There's only three choices. We have to do one of these three things, but we can only do these three things, not anything else.

So the first two choices that the FDA has given to us is the Choice 1, primary culture, and Choice 2, LVDS, which stands for large volume delayed sampling. Those are just two different types of tests. Basically, under both of those methodologies, you take a sample of the platelet, and you test it to see if it has bacteria in it. If it does, you throw the dose away, and you move on to the next dose. They're just tests. They're different types of tests, but they're tests.

Choice 3, very, very different from the first two. Pathogen reduction is not a test. It is a technology where you take the platelets out of the donor's arm into a bag. You then add a DNA cross-linker to the bag, and you subject the bag to ultraviolet light. And that process inactivates the bacteria that may be in that platelet bag, as well as other pathogens that might be in there, other viruses, other parasites that might be in there. So pathogen reduction doesn't just deal with bacteria like Choice 1 and Choice 2. It also inactivates other bad things.

The other thing -- and this is not in dispute here, this is right out of the FDA -- what pathogen reduction takes care of is pathogens we know about today and even ones we may not know about. The classic example is Zika. A few years ago I had never heard of Zika, but then it was all over the news as a new virus that was really having disastrous impacts on babies and pregnant women. The FDA said: Pathogen reduction, that

takes care of Zika. It inactivates Zika. If you use it on platelets, those platelets are now safe to transfuse in the patients. You never have to throw those doses away. You can inactivate the Zika, and they're now safe to be transfused, all in a one-step process. It takes care of all the bad things in one step.

And right now today, we don't know what the next Zika is going to be. We may not have named it, we may not have even discovered it yet, but pathogen reduction right now today is already taking care of things we don't even necessarily know about in those platelet doses that are being transfused into patients.

Where does Verax fit into this process? It has a very narrow role to play here. Verax fulfills a second step in Choice 1 and sometimes in Choice 2. What I mean by that, in Choice 1, the FDA said the blood center has to do primary culture before it can release platelets to hospitals. But those, if you just do Choice 1, when they get to the hospital, the hospital is not permitted to transfuse them yet. They're not safe for transfusion. The hospital has to do a second step. The blood center has released them to the hospitals, but the hospitals have to do something with their own personnel and at their own expense. The hospital has a choice: They can redo the first culture again, just do that same primary culture again -- it's called "secondary culture" -- or the hospital can

buy one of Verax's tests for the second step of the process. And once the platelets have passed, sometimes Verax fills that second role in Choice 2 with LVDS for a very specific type of LVDS platelet called LVDS 36, but that second step at the hospital is the role that Verax plays.

The FDA has not approved Verax's test as a standalone method for bacterial mitigation. No blood center and no hospital can use Verax by itself as a way to satisfy federal law requirements to mitigate bacteria. It's always a second step in a process after the blood center has already done some form of bacterial mitigation. Again, not in dispute, right in Paragraph 82 of the complaint.

So the Red Cross, of course, like all blood centers, had to make a choice: Which of these things did it want to do? And it carefully studied the three options the FDA gave to it and decided, for reasons I hope are obvious, that it was going to pick Choice 3 instead of Choice 2 or Choice 1, and that is because that pathogen reduction deals with more than just bacteria. It takes care of other bad things too; and because it inactivates the bad things, you don't have to throw doses away.

THE COURT: You keep talking about Choice 3 as being the best choice, and the way you describe it, I certainly understand your position, but none of that's in the complaint.

MS. GIORDANO: So none of it is in the complaint about

how these processes work?

THE COURT: Well, just on a motion to dismiss, I'm sort of bound by the four corners of the complaint. I mean, for purposes of my ruling, which is the preferable one is really not before me.

MS. GIORDANO: So what I would say about that is, what is in the complaint is the FDA's December, 2020 guidance document --

THE COURT: Yes.

10:26 MS. GIORDANO: -- which, you know, is a very thick document with actually everything I just told you is in there. It just describes these three processes, how they work.

THE COURT: Does it say Choice 3 is the best?

MS. GIORDANO: No, it does not. It does not. And in fact, I know that Verax is going to say this, so I want to come right out front and say it: For purposes of bacterial mitigation, the FDA has been very clear that it believes all three of these choices are okay for purposes of bacterial mitigation. It did not say, "You should pick Choice 3,

10:26 everyone," that is true, and I know Verax is going to say that.

My point is that when you are given these three choices, what the Red Cross did was look at them and say, "Well, I have only these three choices, and I have to do one for bacteria, so I'm going to pick the one that does more than just bacteria. I get more things accomplished in one step than

if I picked Choice 1 or Choice 2." That's all I'm saying.

This case, of course, as your Honor knows, is about the fact that Verax would prefer that the Red Cross had picked Choice 1, I think primarily maybe to some extent Choice 2, but it does not like the fact that the Red Cross picked Choice 3.

THE COURT: And does the Red Cross do Step 3? It does not. It's another company called Cerus, right?

MS. GIORDANO: We perform the pathogen reduction, but that is a great point. Thank you for pointing that out. The
10:27 Red Cross does not own the pathogen reduction technology. We have to buy it from a third party --

THE COURT: The technology is the product?

MS. GIORDANO: The technology is a manufacturing process, right? Remember I talked about the DNA cross-linker, the ultraviolet light? It's a whole process. You have to take the platelets out of the arm in special kits to use them on the machines. It's a -- I mean, Verax makes a little fun of us in our brief for calling it a "manufacturing process." That's not our words. That's actually the FDA's terminology because this
10:27 is far more complex than I certainly have ever imagined. You don't just take it out of the arm, bag it up and ship it off. It is an immensely complex --

THE COURT: It's a much narrower point.

MS. GIORDANO: Yes.

THE COURT: So essentially the American Red Cross buys

this technology from another company?

MS. GIORDANO: Yes.

THE COURT: They're not selling this technology?

MS. GIORDANO: No. We use the technology in our manufacturing process that we buy from a third party.

THE COURT: And you don't have to have a separate -- it's not like a separate rapid test for each blood -- it's one -- you bought it once, and then you use it on everybody?

MS. GIORDANO: We have to buy kits, and the kits come to us, and we have a contract with Cerus in order to be able to apply pathogen reduction to each dose as we do that work.

10:28

THE COURT: A kit per dose, is that it?

MS. GIORDANO: Yes.

THE COURT: Okay.

MS. GIORDANO: Okay, so you mentioned, and I think you were absolutely right, that this is a case where there is a lot that's going on in antitrust claims, and we've made several different arguments. I was trying to think about how to simplify our point for the Court in this case, what is it that I think most fundamentally is wrong with Verax's antitrust theories; and I think, I hope maybe, one simple way to explain it is the famous Footnote 40 from the Supreme Court's *Jefferson Parish* case in 1984 that both parties cited.

10:29

What the Supreme Court said there is, "The antitrust laws do not give a purchaser the right to buy a product that

the seller does not wish to offer for sale." And the example they use is, "A grocer may decide to carry four brands of cookies but no more, and if the customer wants a fifth brand, he can go elsewhere, but he cannot sue the grocer even if there is no other in town."

And this case at its core is about the fact that Verax wants to use the antitrust laws to force the Red Cross to sell a fifth brand of cookie, except we're not talking about anything as innocuous as a cookie. We're talking about a 10:30 lifesaving blood product, and they want to use the antitrust laws to force the Red Cross to pick Choice 1 or Choice 2, even though Choice 3 deals with more bad things than just bacteria.

THE COURT: But you're once again going beyond the four corners of the complaint. Essentially all I have right now is, the Red Cross prefers this third approach, the one-step rather than the two-step.

MS. GIORDANO: And honestly, your Honor, that is *Jefferson Parish,* Footnote 40. You don't even have to go on to my good reasons for it. You can skip that there's a very good 10:30 reason for Step 3. *Jefferson Parish* says, for no other reason, if we just simply only want to offer Choice 3, we don't have to also offer Choice 1 and Choice 2. The antitrust laws don't make us have to do that.

THE COURT: What is the market power of the Red Cross? What percentage of the platelets does it have?

MS. GIORDANO: Again, I'm constrained, I think you would tell me, by what the complaint alleges. The complaint alleges 40 percent. I don't believe it is that high, but that is what the complaint alleges. And I'm going to abide by the Rule 12 obligation, so that's what I have to go with.

THE COURT: Okay, 40 percent of market, is that enough to be a monopoly under the laws?

MS. GIORDANO: No, it is not. It is not.

THE COURT: -- higher.

10:31 MS. GIORDANO: You are absolutely right, it is not. And the point is that even under these allegations, 60 percent of the market, what they allege is, we're selling today the 40 percent. That doesn't mean those people have no other choices. It just means today they're choosing to buy from us. There's 60 percent of the market according to Verax, at least, that is getting their platelets from some other source that's not us.

THE COURT: All right, thank you.

MS. GIORDANO: Okay, so let me now go to the specific

10:31 arguments that we have made. The first one is antitrust injury. As the Court may recall from its prior cases, antitrust injury is an essential element of every antitrust claim. So this particular argument that Verax has not pled antitrust injury would take care of all three of their antitrust claims for the same reason: It is an essential

element of the claim, and it's an element that requires Verax to plead that it has suffered an injury from a competition-reducing aspect of the defendant's behavior. It's a prudential concern. It's created by judges on the theory that we don't want everybody who may be claiming to have been tangentially injured by an antitrust violation to have standing to come into court to sue.

So the courts, they come up with some general categories of the types of plaintiffs that are found to have suffered a cognizable antitrust injury and the types who have not. And what those cases, if you distill them down, they say essentially is: Typically only consumers or competitors of the defendant in the allegedly restrained market have antitrust injury, and on the flip side, typically, parties who have claims that are just derivative injuries, such as suppliers or potential suppliers to the defendant's customers, those types of parties don't have antitrust injury that's cognizable under the antitrust laws.

I don't believe there's actually any dispute about these principles here. The dispute is that Verax contends it has done enough in the complaint to allege that it is the Red Cross's competitor, and we don't think it has.

So "competitor" under the antitrust laws has a very specific legal meaning. Two companies are competitors when they sell products that the customers believe to be reasonably

interchangeable. That's the *Flowvac* case from the First Circuit, 817 F. 3d 849. And Verax and the Red Cross simply don't sell products to hospitals that hospitals believe to be reasonably interchangeable with each other. We don't compete, these two companies do not compete for any hospital business. The Red Cross sells platelets that it has manufactured in compliance with its FDA obligations, right? We have to do one of those three bacterial mitigation methodologies, and Verax sells an aftermarket test that some hospitals in some circumstances may choose to buy in addition to, but never in lieu of, Red Cross platelets.

10:34

So if you think about it, even if we did Step 1, which is what Verax wants us to do, the Red Cross is still selling, would still be selling platelets that have had bacterial mitigation done to them. Red Cross would have done primary culture and testing on those platelets and would sell those platelets to the hospital, and then the hospital might -- might decide to buy Verax's test. But they're never substituting a product we sell for what Verax sells, and that means we're not competitors within the meaning of the antitrust laws.

10:35

What Verax is is a supplier, an aftermarket supplier to some hospitals that also have bought something from the Red Cross, and under antitrust injury doctrine, that means they have not stated a cognizable antitrust injury.

I'm going to go on to the tying claim unless you have

more questions about antitrust injury.

THE COURT: No.

MS. GIORDANO: So for the tying claim, I will confess to you that it took us a little while to get to understand what Verax specifically was alleging were the two products that we were tying together. Before we filed our motion to dismiss, we wrote to them and said, "We're not sure what the complaint means, here's how we're interpreting it," and we didn't get a lot of confirmation back. So I confess to you that our briefs had to shift because in their opposition, they finally made clear what it was they were actually alleging here; and now that we know that, it is actually a little bit simpler than I even thought.

So what a tying claim is, is that a party sells one product called the "tying product" on the condition you also buy a second product. Basically, "I'm not going to sell you this one thing you really want," the tying product, "unless you also buy this second product." That's the threshold aspects of a tying claim. And so a threshold predicate of the claim is that the defendant actually sells that tying product, right? That's kind of baked into the whole theory, that you sell the thing defined as the tying product. But Verax doesn't allege that here. What Verax alleges --

THE COURT: You're saying -- wait a minute -- the seller has to own both the tying and the tied product? No.

MS. GIORDANO: Not that it has to own both; that it has to actually sell the tying product, meaning the product over which you supposedly have market power and control.

THE COURT: So the tying product would be the blood, and the tied product would be the process for cleaning it?

MS. GIORDANO: Exactly, exactly, and let me pull that apart. The tying product, according to Verax, is platelets on which no bacterial mitigation has been done.

THE COURT: Right.

10:37 MS. GIORDANO: And the tied product is the bacterial mitigation that you do on the platelets. Those are the two products. As a matter of law, the Red Cross does not sell and cannot sell platelets where no bacterial mitigation has been done to them. That's the regulation we just looked at. That tying product that they say that we sell that we have monopoly power over, we cannot legally sell it as a matter of law, and we don't legally sell it. The only thing the FDA allows the Red Cross to sell is platelets that have had one of those three forms of bacterial mitigation done to them. We can't sell raw

10:38 platelets.

And I want to point out that this is not a function of whether customers would prefer to buy raw platelets, unmitigated platelets from us. That does not matter, the Supreme Court tells us in *Jefferson Parish*, right? Because our question is, is this a product that people could buy if they wanted to,

easily could buy if they wanted to? And the answer here for the tying product is "no." If a hospital came to the Red Cross today and said, "Actually, thank you very much. We don't want any bacterial mitigation from you at all. You just take the platelets out of the arm and send us the doses --"

THE COURT: Yes, but here's what -- I mean, what Verax is saying is that your product is $150 more per dose expensive than theirs. So could a hospital go to them and say, "We just want your product with Step 1"?

10:39 MS. GIORDANO: So the answer is, the Red Cross doesn't want to offer a Step 1 product to sale for hospitals, right? That's the Footnote 40. We don't want to have to offer a brand of cookies. We only want to offer the brand of cookie that we want to offer, which is --

THE COURT: It does have a big price impact, right?

MS. GIORDANO: Well, it has a big price impact for reasons we can't talk about, right, because it does very different things.

THE COURT: You're saying it's a better mousetrap, but

10:39 I can't do that right now.

MS. GIORDANO: Right, I understand that. I understand that, but you can do this on the complaint without having to go outside the complaint. What you can recognize from the four corners of the complaint, and from what the FDA guidance document that is cited in the complaint says, you can recognize

that Verax's test is the second step in a two-step process, where somebody, a blood center, has already spent time and money doing the first step, and then the hospital has to spend time and money to do the second step. That's right in the complaint. So your comparing Verax's $25 test doesn't account for all the expense it takes to get to that second step, right? You're not comparing apples to oranges. Does that make sense? PRC's one step, one process, $150. Verax's test is the second step in a much larger process, and they're only comparing the price of their product, and they're not factoring in all the money it takes to get to that second step before you can even use Verax's product.

THE COURT: All right.

MS. GIORDANO: Okay, I believe that's actually all I have on tying. Would you like me to move on to exclusive dealing and attempted monopoly?

THE COURT: Well, again, you're almost out of time, so --

MS. GIORDANO: Okay, this one is really simple as well, and I can do it very quickly because it's the same reason for these two claims. And, by the way, these are all independent legal arguments. The exclusive dealing and the monopoly claims fail for the simple reason that I don't see any evidence in the complaint of cognizable allegations of harm to competition. And this principle, right, is that you have to

show not just harm to Verax; you have to show harm to competition in the marketplace generally. Something the Red Cross has done has had to reduce the number of competitive options available in the marketplace.

And, yes, I see, I know that Verax has a whole section of their complaint called "Harm to Competition," and I know they use a lot of buzz words there. But what the facts of the complaint actually show, really, truthfully is alleged, is that there hasn't been a reduction in the types and technologies of
10:41 bacterial mitigation that are available in the marketplace. There's an increase. Back before the FDA approved pathogen reduction to be one of these methods, before 2015, primary culture was really all there was you could do. So of course that was great for Verax. They were pretty much the only game in town because you could only do Choice 1. But then the FDA approved LVDS, and then they approved pathogen reduction, so there's been an increase in the number and technologies and options available for bacterial mitigation, not a decrease. And Verax is complaining about an injury it has suffered from
10:42 an increase in competition with them. There are new technologies to do bacterial mitigation that there did not used to be, and that has made Verax's product less commercially relevant. That is not an antitrust violation, your Honor.

I'll stop there. I know I'm out of time.

THE COURT: Yes, thank you.

(Discussion off the record.)

THE COURT: Maryellen, do you know, is our 11:30 in person?

THE CLERK: No. It's by video, and I emailed them, so it's ready to go at 11:30.

THE COURT: Okay, all right, thanks.

All right, go for it, Verax.

MR. ABELES: Thank you, your Honor. So we just heard a summary of the defenses in this case, which are essentially
10:43 that we lack standing. The complaint dealt with antitrust injury. Antitrust injury is actually an element of standing. It doesn't really matter for purposes of this argument. Verax doesn't sell the tying product, and that there's been no harm to competition. We already talked about the last point. All three of these points are actually different ways of saying the same thing, that ARC and Verax are not competitors. That's really the issue as to each of these defenses.

There's talk that we changed our relevant markets and so on. True confessions for me, I'm not sure why, because we
10:44 always defined the tying market as the FDA-cleared products for bacterial mitigation in the guidance-type documents that have been pointed out by both parties. So, yes, your Honor recognized, and as counsel conceded, the FDA doesn't recommend one over the other. Bacterial detection devices, that covers LVDS, and our rapid-test pathogen reduction, that's the

technology developed by Cerus that ARC now employs, and it's either a single step or a two step. The Cerus technology involves one step; ours involves two.

So here's what the market looks like, your Honor. Prior to October, 2021, when ARC began tying its blood platelets to a bacterial mitigation service, the PRT service, some hospitals went with this single step, the PRT process. Most did not. Most did not. What they did was, as counsel pointed out, they combined a primary culture, which tests for 10:45 carbon dioxide. It's a much simpler test than ours. Verax's test tests for diseases, not just the presence of carbon dioxide. The reason you test for carbon dioxide is, that indicates bacterial growth.

So in this free market, hospitals chose our product 75 percent of the time. And we did, by the way, your Honor, talk about the advantages and disadvantages of the products. We have a whole section in our complaint. One, why would the market vote for Verax? Well, there's a variety of reasons: It's less expensive. It does not degrade platelet quality, 10:46 very, very important. As we allege, there's a significant degradation of platelet quality when you use the Cerus. So what does that mean? You've got to buy the more expensive product -- it is much more expensive -- and -- and you have to buy more blood.

THE COURT: But this 75 percent, it's before the FDA

approved these two other --

MR. ABELES: No, your Honor. These were all in the market starting at least in 2015, I believe. I'll stand corrected on that, but not all of these products that you see on this slide were in the market prior to the time when Verax was the dominant player in the market.

And so what happens? What happened in this case, your Honor? Well, they began to tie their platelets and their bacterial mitigation service, so Verax gets foreclosed from its
10:47 sales to its own customers, and, by the way, to the Red Cross's customer there. If it wants to offer that customer that it thought PRT was better, make a pitch, it you can't do that. Neither can anyone else, your Honor. The reason there's harm to competition here is because if they knew --

THE COURT: Can I stop you. Can't they use any method that the FDA approves? Like, the FDA gives you three choices, and can't they decide to do one?

MR. ABELES: They can pick the one they want, your Honor, but there is a rule against tying. Monopolists do not
10:48 have the same freedom in our economy under the Sherman Act that other companies do. Antitrust --

THE COURT: Is 40 percent enough to be a monopoly?

MR. ABELES: It is. Yes, it is, your Honor. They didn't argue whether they have market power, monopoly power. That's not one of their arguments, so there were three --

THE COURT: Okay, I'm sorry. Just I've had other --

MR. ABELES: That's okay, your Honor, but let me just explain why that is, okay? If you have a market where you've got one party with 40 percent, another with 30, another with 20 or 30, yeah, the one with 40 probably does not have monopoly power in that situation because when it raises its prices, folks can shift to the other two dominant players. In this market, though, you've got one guy with 40 percent, and the rest of the market is -- it's called "atomized" -- a bunch of very, very small players.

10:49

THE COURT: I see.

MR. ABELES: So that's why 40 percent. And I understand your point, usually it's higher, but it absolutely qualifies here.

And so what happens after this tying, as I was saying just a minute ago, your Honor? Antitrust law is an imposition on trader, on business freedom. It is. The Congress has decided there are more important qualities than, you know, freedom of contract, freedom to sell. So there is a rule against tying when the one doing the tying has monopoly power. If they get it, they could tie together anything they want.

10:49

So what happens after this change? Given this fourth choice, hospitals choose Verax about 5 percent of the time. It's not in the complaint, admittedly, your Honor, but my client told me it's around 1 percent. They're going out of

business. They're being completely driven from the market because of this, because of this tying.

Now, your Honor, you did mention earlier, and I understand your point, that, "Oh, this is a complicated case, this is very different," and I would beg to differ because this is really how you should look at the case. This is --

THE COURT: You know, I was struggling to figure out what that was a picture of.

MR. ABELES: Sure, so that's tuna salad on your left.

10:50 THE COURT: That's a salad, not a bowl of oatmeal?

MR. ABELES: No. Thank you, your Honor. That is a bowl of tuna salad, and, of course, you see what the product is on the right. Their argument is that because you have to combine Bumble Bee tuna with mayonnaise to make tuna salad, then Bumble Bee tuna -- this is the argument -- Bumble Bee tuna does not participate in the market for tuna salad. That's their argument. And it may be, your Honor, that in a weird case like this one, after expert discovery and so forth, the facts may show that Bumble Bee tuna has such grand equity that

10:51 people wouldn't substitute to a readymade salad. But you can't say it's a matter of law that Bumble Bee tuna, because it has to be mixed with mayonnaise, does not compete in the market for tuna salad.

And this I would encourage you to think about when you think about this question of we're not a perfect substitute.

Neither is Bumble Bee for the tuna salad you see on the left.

So where are they going wrong? Why do they end up in this place, your Honor? It's because they're focusing on the supply side, differences on the supply side, when they need to be focused on the demand side. This is a First Circuit case, but it's quoting a very important Supreme Court case called *Brown Shoe*, in which, you know, when you want to figure out who's in the market, you look at the cross-elasticity of demand. And that's just a fancy way of saying, changes in demand of one product impact inversely the demand of another product, and if that happens to a significant degree, they're in the same market.

10:52

And what did we just see? What did we just see? We saw a change in demand, market demand, 75 percent. We saw a change in demand, an artificial depression of our market share and artificial elevation of the Red Cross's, and a complete shift in share. That's cross-elasticity of demand. That's exactly what cross-elasticity of demand means, and that's what you should be focused on, not the supply side differences that the Red Cross emphasizes.

10:53

Now, the second point is also very -- this is from a Supreme Court case called -- it's known as *AmEx, Ohio v. AmEx*, but what it's quoting is an even more important Supreme Court case called *United States v. Grinnell*. Let me tell you about that for a moment because it has force here. In *Grinnell* the

defendant sold safety systems, burglar alarms, fire alarms and so on. The claim was, "Hey, a burglar alarm is not a perfect substitute for a fire alarm. So you only sell fire alarms; you're not in this market." And what Grinnell said and what Ohio picked up on is that "Wait a minute. We need to focus on commercial realities here. That's what we do. If you need to combine different products and services like these two into the same market in order to reflect commercial realities, you should do so," and that's what happened in Grinnell. It was basically a home safety market that featured a bunch of different --

10:54

THE COURT: Can I just say that I understand that we're not really here for the motion to dismiss, but assume for a minute that the Red Cross believes, in good faith, that their technique, which is FDA approved, is the better one and provides a better product, why can't they sell the product that they think is the best?

MR. ABELES: It's the same answer as before, your Honor: There is a rule against tying when there's a monopolist who can force the choice of its consumers.

10:54

THE COURT: They're not really in the market of producing these cleaning products.

MR. ABELES: So, your Honor -- and thank you for bringing that up -- so they sell bacteria mitigation services. They use machines that they buy, of course, they use machines

that they buy to sell a service, bacterial mitigation services, which uses the Cerus technology. But you don't focus on the inputs, okay? You focus on the outcomes: What are they providing? So they sell blood. If you want PRT instead of a primary culture, an LVDS blood platelet, you pay $150 extra. That's how you know that these are products tied together and that ARC is providing this service in this market.

In order to perform the service, they've got to buy some things. They've got to buy this PRT system. But then
10:55 they resell that to their customers in competition with the other players in the market. That's just the answer to that.

THE COURT: So you're basically saying, any producer of a product that picks one element of that product that's more expensive is basically tying, not offering the customer a cheaper element?

MR. ABELES: I didn't understand.

THE COURT: Like a car. Let's say you have a car, and you want one form of a carburetor rather than another form even if it's more expensive, you'd say that's tying the carburetor,
10:56 even if you don't sell carburetors? Maybe that's a bad example but --

MR. ABELES: Okay, let's say this, your Honor, and if I'm not understanding it, then -- and I didn't mean to interrupt you -- there's a monopoly of cars, which there is. But let's say there's a car seller with fifty percent of the

market, if --

THE COURT: Likes one carburetor rather than the other because they think --

MR. ABELES: Well, the carburetor, that kind of goes into the --

THE COURT: Into the car, right.

MR. ABELES: That's an element of the car. That's not a separate part of the car. That's not a service. So if this monopoly car seller required you to go to his car wash, and I'm a car wash owner and I perform car wash services, if they're exploiting their monopoly in order to threaten a monopoly in the car wash business, that's a problem. When it's all part of the same product, yeah, you don't break apart the car. We can't break apart that blood --

10:56

THE COURT: Why isn't that a closer analogy, because you're basically selling just the little bag of blood?

MR. ABELES: You're selling a bag of blood that's had a service performed on it, a bacterial mitigation service. Today, by the way, your Honor, they still are. They're not selling all PRT. They're selling some platelets that are primary cultured. They use the LVDS technology and so forth. So it's not one product. And this is reminiscent of Microsoft which tried to argue that "Hey, our browser, that's really a fundamental part of our operating system," so this is a good example, your Honor, based on the car.

10:57

THE COURT: All right, I see.

MR. ABELES: So Microsoft said, "Hey, look, this browser in our operating system, they're all integrated, and they all work together as one operating system." And the court said, "No. No, these are separate. These are separate. There's a browser market and there's an operating system market." And Nexgate, which was the foreclosed competitor there, nobody said to Nexgate, "Hey, you don't sell operating systems that have browsers integrated into them. You don't 10:58 sell tuna salad. You just sell mayonnaise. You just sell Bumble Bee." That was not an argument because it would not have worked. You don't have to have an identical -- that's why tying is so powerful -- you don't have an identical product line when you're (Inaudible).

And so when you look at the cross-elasticity of demand, not the supply differences, and when you look at the commercial realities, you can see that they participate in the same market. And *Jefferson Parish* is actually a good example of this commercial realities. *Flamingo* goes to a point that 10:59 you focused on earlier, your Honor. They acquired, they bought -- as ARC emphasizes, "We buy this technology" -- they bought anesthesia services. They had a contract with a third-party anesthesia group, and then they offered that as a bundle. I'm not saying they used this term "commercial realities," I don't remember if they did, but they made the

same point.

What you do is, you look at whether this arrangement has the competitive consequences that tying addresses. Of course, that's the competitive concept. And so, you know, *Jefferson Parish*, while it has a footnote that the other side finds interesting, the actual case and the actual tie that was offered there, that's really what's worth focusing on here.

There is insinuation in the briefing -- I guess I didn't hear it in the oral argument, but there was a line somewhere along the line, "It's not illegal for us to use your product." I'm not sure if they said that, but there's an insinuation, but I just want to end that debate because there is not a legal --

THE COURT: Not a legal? I'm sorry, I don't understand.

MR. ABELES: So it's a point that you caught earlier with counsel, your Honor, that these are all FDA-approved products. They are allowed to primarily culture their -- they are in compliance when they sell not just PRT platelets but platelets that have been primary cultured as well, which our product, like the Bumble Bee, works with another, like the mayonnaise, and that is the primary culture product.

So because they do compete, because when you look at the cross-elasticity of demand and you see a share shift between these two entities, and when you look at the commercial

realities -- we were the driving force in the market, they tied their product, we lost our market share -- you can see that they are in the same market, and we've certainly plausibly alleged exactly what happened.

THE COURT: But isn't it -- you know, sometimes you see sort of, like, the Cerus product is a disruptive technology. It may be that it was better.

MR. ABELES: That's why we'll have a trial, we'll have summary judgment and a trial, and maybe that's the case, your Honor. I don't think -- I think there's a reason that the market favored our product. It's equally effective. Blood that's contaminated does not go into a person after our test is used, and that's what the FDA cares about. That's why it has three ways to make sure contaminated blood doesn't get into a person. But I think what you're going to see as this case progresses, your Honor, is the reason that the market favored our product is, it doesn't lead to degraded platelets. You use less blood.

THE COURT: Well, it's cheaper.

MR. ABELES: It's cheaper.

THE COURT: The question is, how much are you willing to pay for the perfect blood as opposed to maybe someone catching something else, some other kind of disease other than something to prevent sepsis? But what you're saying is that I have to wait for a trial for that, so I --

MR. ABELES: Well, I just don't think that counsel for Verax and counsel for ARC to get into it the day at the motion to dismiss level --

THE COURT: I agree with that.

MR. ABELES: -- is better. But I think that despite theirs being more expensive, I disagree with this notion that they're the disrupter and all that. There's a reason that the market favored our product, your Honor, and I think that --

THE COURT: And you'd say not just price?

11:03 MR. ABELES: Absolutely not just price. And let me just emphasize this one more time, your Honor: When you use the PRT technology, it reduces the quality; it degrades the quality of the platelets, so somebody who gets transfused needs more transfusions, which are dangerous. That's why there's all these rules. The hospital has to buy more platelets. So this tie not only allows them to sell this tying process at, you know, a monopoly price, obviously; there's no reason they would charge anything less because people need to buy it.

So not only you're paying -- let me complete that

11:04 point. Sorry, your Honor. Not only are you paying more for the tied product, the service, you're paying more -- you have to buy more blood because the platelets are degraded by 30 percent or something like that via the PRT. So this tie actually -- this is rare -- this actually helps them on both sides of the tie. They make a monopoly profit on the tied side

and on the tying side.

And so these points, your Honor, the fact that they compete, it costs less, elasticity of demand proves it, the commercial realities prove it. It defeats each one of the arguments that they raise. Because ARC and Verax are competitors, Verax's foreclosure is an antitrust injury and Verax's standing. ARC is not a buyer in the tied market; it is a seller. It charges separately for its bacterial mitigation service. It's a distinct product. Obviously we're their competitor. We only sell this. It's separate from blood platelets. And foreclosure of competition from Verax and all others is harm to competition. This is absolutely not a case, your Honor, in which we are just claiming harm to ourselves, okay?

As I mentioned, if there was an innovative firm that offered a product that was ten times better than all the products you see here and one-tenth the price, how many sales would they get in the market? Zero, zero, because they're foreclosed from this market because of the bundle. That is harm to competition, along with our foreclosure, which is almost always considered a harm to competition. There's a foreclosure of another competitor, bioMerieux, as well.

And look at this. I mean, the harm to competition is obvious. Higher prices, we think lower quality, that's what we're going to argue, but we'll see, for a product that when

they had a free choice, the hospitals, most of them did not want.

Thank you, your Honor.

THE COURT: Thank you.

All right, so I think we do have a few minutes to talk briefly about the torts.

MS. GIORDANO: Could I just spend 30 seconds on the antitrust claims, one more moment, your Honor? Just two quick points? Is that okay?

11:07 THE COURT: Yes.

MS. GIORDANO: One is -- I want to underscore this because I didn't hear it in anything Mr. Abeles said -- federal law does not permit the Red Cross to sell platelets unless we have done one of the three approved types of bacterial mitigation. That's why the tuna, the Microsoft, those analogies do not work. If federal law said you cannot sell tuna fish unless you have mixed it with mayonnaise, that would not be a tie either. There would be nothing wrong with selling tuna fish mixed with mayonnaise if federal law says that's the 11:07 only way you can sell it. And federal law says we have to do one of those three things. Verax just doesn't like the one of the three that we picked.

The second thing I want to say is, we will be able to show that almost everything Mr. Abeles just told you is not true in the real world facts, but I can't do that here today.

It's a motion to dismiss, and I don't want to --

THE COURT: It's making me hungry for a tuna fish sandwich.

MS. GIORDANO: I don't want to take us backwards, but it is a reason Congress does not want us to be subject to the Sherman Act, because we are at risk of having to spend a lot of money to try to explain the real-world facts, these claims are not true; and that's going to waste resources that we are supposed to be using to do the important task Congress has given to us. Thank you.

11:08

MR. ABELES: Your Honor --

THE COURT: I gave her extra. You can go.

MR. ABELES: Your Honor, I will always stand corrected if I make a misstatement, but I've spent a lot of time talking with my experts, which are my clients, and they agree with me. And I believe that everything I said was true, but I'm certainly not misleading the Court, and I just kind of generally object to this naked insinuation.

THE COURT: All right, thank you. Let's go to the torts because I was trying to think out loud. I just think that this is a very, very difficult case, and I understand antitrust. If I were to say that the Red Cross was a person and it was a viable claim -- I'm not saying I'm going to do that -- would that be something that would make sense to go up on an interlocutory basis? If I say it's not a person and I

11:09

say but there are potential tort liabilities, I think I'd keep it to work through the tort liabilities. I'm just trying to figure out a pathway that makes sense because, of course, I'm going to stay discovery till I sort this all out.

I recently had a very close insurance case Law 360 is saying they had vigorous debates about, but the First Circuit took it on an interlocutory basis, so -- and I recommended that they take it because why spend all the money litigating? I think the personhood thing is very difficult myself. There are really strong arguments both ways. It almost should be one of these law school moot courts. Maybe I'll suggest that to the law school.

But why don't we just briefly walk through these torts and think about that issue. Or maybe what we should do is just see how I come out, which I honestly don't know right now, and then ask you your views on that issue.

MS. GIORDANO: Okay, thank you, your Honor. Yes, I think that that sounds like a very sensible way to proceed. I do think the person issue is so important enough to the Red Cross and so fundamental to the outcome of this particular case that it would be a perfect candidate for that review, depending on how you came out.

THE COURT: My law clerks and I will sort through it. All right, go ahead.

MS. GIORDANO: Thank you. Okay, we are -- wow,

there's a lot here today. Let me see if I can get my slides up on state law claims. So --

THE COURT: I'm happy, by the way, if you're all tired, to just rest on the papers on it.

MS. GIORDANO: I would be happy to do it. If Mr. Abeles wanted to do that, that would be fine.

MR. ABELES: I think those issues are squared up for your Honor in the papers and reiterate some of the points that we made, but if that's not going to be helpful to you, then this might be a place to stop.

11:11

THE COURT: Okay. Well, I will look at the papers on the torts. You should not expect an opinion soon. I like to say that, but I think discovery needs to be stayed because I really am not -- on this threshold issue, it's just a very difficult issue of personhood. And the question I always ask everybody, so it's not meant to be any kind of indication of anything, has there been any talk of settlement?

MR. ABELES: No, your Honor.

THE COURT: Is there any interest in that?

11:11

MR. ABELES: We're always open to speaking with the defendant about potential settlement.

MS. GIORDANO: We would always welcome a conversation as well, your Honor.

THE COURT: One thing that comes to mind, suppose you had a hospital chain that wanted to go with the two-step, would

the Red Sox be willing -- Red Sox, it shows you where my mind is at -- would the Red Cross be willing to sell to that hospital with the one step?

MR. ABELES: I'm sorry?

THE COURT: What?

MR. ABELES: Was that a question for me, your Honor?

THE COURT: I'm just thinking about, is that a way to settle this? Not with money but with an agreement that, let's say, one of these mega chains?

11:12 MR. ABELES: If they wanted to undo their tying, your Honor, then I think we would seriously consider --

THE COURT: Well, no. They tie it unless the hospitals demand something else.

MR. ABELES: The hospitals did demand something else, your Honor. Seventy-five percent of them did. They can't buy our product anymore. They don't need it.

THE COURT: Excuse me. The 75 percent bought it before. I mean, I'm just saying. I don't know the position of the Red Cross on that, but, anyway, I don't pretend to know

11:13 this industry well. I just got to it in the last week. So I just wanted to know whether you wanted to think about that at all and go to a mediator or whether you just need some threshold rulings.

MS. GIORDANO: I think we need some threshold rulings in this particular matter, your Honor. We are always open to a

conversation -- I don't want to suggest that we are not -- but I think that these threshold issues are so critically important to really even being able to have those conversations, that I do think we need to know sort of some of these threshold issues.

THE COURT: Well, I get it. So I will take this under advisement. All discovery is stayed, and I'll do my best. I said to my law clerks and they said to me back, "This is excellent briefing." You don't usually get such high-quality briefing on everything. And I loved, loved the slides, so thank you very much.

11:13

MR. ABELES: Thank you, your Honor.

MS. GIORDANO: Thank you, your Honor.

THE COURT: Thank you. Bye-bye.

(Adjourned, 11:14 a.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter, do hereby certify that the foregoing transcript, Pages 1 through 67 inclusive, was recorded by me stenographically at the time and place aforesaid in CA No. 23=10335-PBS, Verax Biomedical Inc. v. American National Red Cross, and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

Dated this 3rd day of October, 2023.

/s/ Lee A. Marzilli
_____
LEE A. MARZILLI, CRR
OFFICIAL COURT REPORTER